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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,013	11/16/2001	Shui-on Leung	18733/1082	7681

22428 7590 03/30/2005

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EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,013	LEUNG ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-32* is/are pending in the application.

4a) Of the above claim(s) *28-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-24 have been canceled.

Claims 28-32 have been added.

Claims 28-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 25-27 are pending and under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

4. The objection to the specification for not including the relationship between the non-provisional applications on the first line of the specification was not addressed in the response filed 3/3/2005 and therefore, the objection is maintained.

5. The objection to the instant application for being a CIP of USSN 09/741,843 because the instant application discloses the limitation of a variable light chain CDR3 consisting of amino acids 95-102, which is not supported in prior application USSN 09/741,843 was not addressed in the response filed 3/3/2005 and therefore, the objection is maintained.

6. The rejection of claims 25-27 under 35 U.S.C. 112, first paragraph, because the specification does not enable the scope of the claims is maintained.

The response filed 3/3/2005 has been carefully considered, but is deemed not to be persuasive. The response states that the examiner has the burden to overcome the presumption that the instant application is enabling and the examiner must give reasons for the uncertainty of the enablement. The response also states that working examples are not per se required to satisfy the enablement requirement and applicant asserts that one skilled in the art would readily be able to practice the full scope of antibodies claimed employing no more than routine experimentation. In response to these arguments applicant has not provided any evidence or reasoning that no more than routine experimentation would be required by one skilled in the art to practice the full scope of then claimed invention. In fact, the teachings of Rudikoff et al indicate that even minor changes in the amino acid sequences of the variable regions can dramatically affect antigen-binding function, thereby indicating the unpredictability in the art. The specification does not provide sufficient guidance or direction as to the general tolerance to modification or the extent of such tolerance in the variable regions; the specific positions of the variable regions which can be predictably modified and which regions are critical for maintaining antigen specificity and affinity. Thus, without more specific descriptions, and without more precise guidelines one skilled in the art could not predictably substitute at least one amino acid in the framework regions of the heavy and light chain variable regions of the LL2 monoclonal antibody with a reasonable expectation of success of maintaining antibody function. The examiner recognizes that compliance with the enablement requirement does not turn on whether an example is

disclosed, however, as discussed above the claims were not rejected based on the absence of an example in applicant's specification.

7. The rejections of claim 25 under 35 U.S.C. 102(b) as being anticipated by Pawlak-Byczkowska as evidenced by Kreitman et al and anticipated by Goldenberg et al and Kreitman et al and Murthy et al are maintained.

The response filed 3/3/2005 has been carefully considered, but is deemed not to be persuasive. The response states none of the cited references describe each and every element of the claimed invention and the rejection should be withdrawn. In response to this argument applicant has not provided any objective evidence indicating that the LL2 antibody claimed is structurally different from the LL2 antibody in the prior art. It remains the examiner's position that the LL2 antibody of the prior art is identical to the claimed LL2 and therefore, necessarily comprises the claimed CDR sequences. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed LL2 antibody with the LL2 antibody of Pawlak-Byczkowska (as evidenced by Kreitman et al) and Goldenberg and Kreitman and Murthy, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed LL2 antibody and the LL2 antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Applicant's remarks with respect to claims 28-32 are acknowledged, however, these claims are not under examination in the present application.

8. The rejection of claim 25 under 35 U.S.C. 102(e) as being anticipated by Goldenberg et al (U.S. Patent 5,776,094) is maintained.

The response filed 3/3/2005 has been carefully considered, but is deemed not to be persuasive. The response states none of the cited references describe each and every element of the claimed invention and the rejection should be withdrawn. In response to this argument applicant has not provided any objective evidence indicating that the LL2 antibody claimed is structurally different from the LL2 antibody in the prior art. It remains the examiner's position that the LL2 antibody of the prior art is identical to the claimed LL2 and therefore, necessarily comprises the claimed CDR sequences. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed LL2 antibody with the LL2 antibody of Goldenberg, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed LL2 antibody and the LL2 antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Applicant's remarks with respect to claims 28-32 are acknowledged, however, these claims are not under examination in the present application.

9. The rejections of claims 25-27 under 35 U.S.C. 102(b) as being anticipated by Leung S. O. or Juweid et al are maintained.

The response filed 3/3/2005 has been carefully considered, but is deemed not to be persuasive. The response states none of the cited references describe each and

every element of the claimed invention and the rejection should be withdrawn. In response to this argument applicant has not provided any objective evidence that the LL2 antibody claimed is structurally different from the LL2 antibody in the prior art. It remains the examiner's position that the humanized LL2 antibody of the prior art is identical to the claimed humanized LL2 antibody and therefore, necessarily comprises the claimed CDR sequences and has at least one framework amino acid substituted from the corresponding murine frameworks, absent evidence to the contrary. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed LL2 antibody with the LL2 antibody of Leung or Juweid et al, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed LL2 antibody and the LL2 antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Applicant's remarks with respect to claims 28-32 are acknowledged, however, these claims are not under examination in the present application.

10. The rejection of claims 25-27 under 36 U.S.C. 103(a) as being unpatentable over Pawlak-Byczkowska et al as evidenced by Kreitman et al in view of Queen et al and Goldenberg et al and Orlandi et al is maintained.

The response filed 3/32005 has been carefully considered, but is deemed not to be persuasive. The response reviews the three basic criteria that must be met to establish a prima facie case of obviousness (MPEP 2142). The response argues that

the cited references either alone or in combination do not disclose all of the elements of claim 25 and the rejection should be withdrawn. In response to this argument, applicant has not provided any objective evidence that the LL2 antibody claimed is structurally different from the LL2 antibody in the prior art. It remains the examiner's position that the LL2 antibody of the prior art is identical to the claimed LL2 and therefore, necessarily comprises the claimed CDR sequences. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed LL2 antibody with the LL2 antibody of Pawlak-Byczkowska as evidenced by Kreitman, the burden of proof is upon the Applicants to show a distinction between the structural and functional characteristics of the claimed LL2 antibody and the LL2 antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Applicant has not provided any arguments with respect to the motivation to combine the teachings of the prior art or provided reasoning why one of ordinary skill in the art would not have a reasonable expectation of success in reaching the claimed invention in view of the teachings of the prior art. Applicant's arguments with respect to newly added claim 28 are acknowledged, however claim 28 is not under examination in the instant application.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the rejection is maintained.

11. The rejection of claims 25-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent 6,187,287 B1 is maintained.

The response filed 3/3/2005 requests that the rejection be held in abeyance until allowable subject matter has been identified at which time applicant will consider filing a terminal disclaimer. In response to this argument, no terminal disclaimer has been filed and the rejection is maintained.

12. The rejection of claims 25-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 20-21, 25-26 and 29-30 of U.S. Patent 5,789,554 is maintained.

The response filed 3/3/2005 requests that the rejection be held in abeyance until allowable subject matter has been identified at which time applicant will consider filing a terminal disclaimer. In response to this argument, no terminal disclaimer has been filed and the rejection is maintained.

Conclusions

13. No claim is allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

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